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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,519	01/03/2002	Daniel Benjamin	ORT-1550	7332

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,519	BENJAMIN ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicants' response to the Office Action mailed 12/15/04 is acknowledged (Paper filed 4/28/05). In the amendment filed therein claim 1 was modified while claims 5-8 have been canceled. Accordingly claims 1-4 are pending and under consideration.

2. Rejections and/or objections of record not reiterated below have been withdrawn.

OBJECTIONS WITHDRAWN

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

4. The information disclosure statement filed 14 May 2002 has been considered as to the merits before First Action.

5. The information disclosure statement filed 13 May 2003 has been considered as to the merits before First Action.

Response to Arguments

Applicants contend that all the documents noted in the Background of the Invention were considered by the examiner. Accordingly the objection is withdrawn.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

6. Claims 1-4 are withdrawn from rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has addressed the noted indefiniteness via arguments and/or amendments. Therein obviating the rejections of record in the paper mailed 12/15/04.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is vague and indefinite because it is not clear what fluorescence wavelength is being utilized. Claims 1 step (a) refers to a wavelength produces at about 484nm while claim 1 step (c) recites the measurement of a wavelength at about 485nm. It is suggested that the claim refer to one wavelength to eliminate ambiguity. Appropriate correction is required.

B. Claim 3 is vague and indefinite in reciting "an enhancing peptide" because it is not clear if this is the same enhancing peptide recited in claim 1 or does the method contain two different enhancing peptides. Please clarify the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-4 are rejected under 35 U.S.C.103(a) as being unpatentable over Biere et al. (US Patent #6,184,351) in view of Murray et al. (Society for Neuroscience Abstracts, Vol.26, No.1-2, 2000 – Abstract No.-84.10) and LeVine (Protein Science, 1993, 2, 404-410).

Biere et al. teach aggregation assays measuring aggregated human recombinant NACP/I-synuclein (column 3 lines 3-18 and Gene Core sequence search – result 2) in the present of a test compound.

In Biere's assay a pre aggregated alpha synuclein solution is added to the test sample and the change in fluorescent detection was measured at 280 nm - wavelength (as an indication of change in aggregation). See figure 3, column 2 lines 38-43, and column 8 lines 26-27. Multiple time points are measured to evaluate the change in aggregation (two different points in time). See figures 3 and 6, for examples.

The human recombinant NACP/I-synuclein composition taught by Biere et al. read on claims 3 and 4 because the claims recite compositions comprising residues 61-90 of alpha synuclein = SEQ ID NO:3 or SEQ ID NO:4. Therefore, the full length 140 amino acid NACP/I-synuclein of Biere et al. includes SEQ ID NO:3 and SEQ ID NO:4.

Biere et al. differ from the instant invention in not specifically teaching fluorescent detection with Thioflavin T (Thio T) at about 484 or 485.

However, Murray et al. disclose an aggregation system detecting compounds that inhibit alpha synucelin aggregation. The results were detected via Thioflavin T. Murray et al. taught that Thioflavin-T appeared to compete with test compounds to inhibit alpha syn aggregation and this could be monitored by the fluorometry assay but not by centrifugation. See abstract.

While, LeVine discloses that Thioflavin T's association with aggregates produces an enhanced emission at 482 nm (about 484 or 485). See abstract and page 405 1st column.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention utilize Thioflavin-T at about 484nm or 485nm wavelengths, in the pre-aggregated alpha synuclein fluorescent detection method taught by Biere et al. because Murray et al. taught that Thioflavin-T appeared to compete with test compounds to inhibit alpha syn aggregation and this could be monitored by the fluorometry assay but not by centrifugation. See abstract. While, Levine taught that Thioflavin-T produced an enhanced emission at 482 nm. See abstract and page 405 1st column.

One of ordinary skill in the art would have been motivated to employ Thioflavin-T along with a test compound in a competitive method so that Thio T would serve not only as a positive marker (complete inhibition) but could also provide information of the test compounds interaction when other inhibitors are present. This would prove valuable in finding compounds to treating neurodegenerative illnesses exhibiting alpha syn aggregation (Parkinson disease/Alzheimer's disease). See Murray et al. abstract. and LiVine page 404.

Response to Arguments

Applicant contends that the claimed method utilizes *enhancing peptides* to expedite the rate of the alpha synuclein aggregation assay and the assays of the cited prior art are prolonged. This argument was carefully considered but not found persuasive because the cited art employs the same enhancing peptides in alpha synuclein aggregation assay (See Biere's wherein aggregated alpha synuclein solution is added to the test sample and the change in fluorescent detection was measured at 280 nm - wavelength (as an indication of change in aggregation). See figure 3, column 2 lines 38-43, and column 8 lines 26-27.

Further, employing human recombinant NACP/I-synuclein compositions taught by Biere et al. that read on claims 3 and 4 because the claims recite compositions comprising residues 61-90 of alpha synuclein = SEQ ID NO:3 or SEQ ID NO:4. Therefore, the full length 140 amino acid NACP/I-synuclein of Biere et al. includes SEQ ID NO:3 and SEQ ID NO:4.

Also, the claims do not indicate a shorter time course for assay progression but merely read on an incubation of sufficient time to allow for a change in aggregation state (claim 1 step (b)). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., shorter time course than the prior art methods) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. For reasons aforementioned, no claims are allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

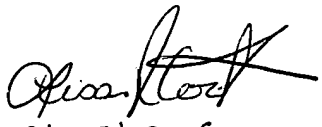
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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